



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/772,365

02/06/2004

Yuh-Shyong Yang

MR1035-1384

5042

4586

7590

04/08/2008

ROSENBERG, KLEIN & LEE

3458 ELLICOTT CENTER DRIVE-SUITE 101

ELLICOTT CITY, MD 21043

EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,365	Applicant(s) YANG ET AL.	
	Examiner LORE RAMILLANO	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/28/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/6/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 12/28/07, applicant amended claims 1-3 and 15.
Claims 1-15 are pending and under examination.

Claim Objections

2. The objection to claims 2-3 and 15 are withdrawn.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

4. The rejection of claim 3, under 35 USC 112, second paragraph, for the reasons stated the prior Office action (filed on 10/2/07), is withdrawn. In light of applicant's amendments, a new rejection follows.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 15 provide for the use of the CMOS in claim 1 and for the use of electronic device in claim 15, but, since these claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

Art Unit: 1797

encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Furthermore, the claim would be indefinite with the incorporation of the process steps since the claim is an apparatus-type of claim.

Claims 1 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Specification

7. The objection to the disclosure is withdrawn.

Prior art rejections

8. In light of applicant's amendments, the rejections over the prior art are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1, 3-9, 11, 13, and 15** are rejected under 35 U.S.C. 102(b) as being anticipated by Zilber et al. ("Zilber," US Pub. No. 2003/0119030).

Zilber discloses a biochemical sensing device, including: a bearing body, which bears a reagent thereon, and the reagent contains a specific compound, a first enzyme, a second enzyme, and a luminol, in which the specific compound and the first enzyme will produce a reaction and then generate H_2O_2 , whereas the H_2O_2 , the second enzyme, and the luminol will produce a chemiluminescent reaction; a sensing element, fabricated by a semiconductor process for sensing the light generated by the chemiluminescent reaction as well as for converting the sensed optical signal into a current signal; a current/voltage converting circuit, capable of converting the current signal into a voltage signal, and an electronic device, which can receive and process the voltage signal so as to perform a quantitative analysis on the specific compound (i.e. [0010]; [0024]; [0048]-[0069]; p. 4, claim 1).

Zilber further discloses the following: the luminol reagent is luminol; the first enzyme is selected appropriately according to the type of specific compound that exists; the second enzyme is peroxidase; the sensing element can be a photodiode; the sensing element is designed for sensing the luminescence light, fluorescence light, and ultraviolet light, or any combination of the three; the current/voltage converting circuit can include at least one current mirror so as to amplify the current signal; the current/voltage converting circuit can include at least one resistor so as to convert the current signal into an analog voltage signal; the current/voltage converting circuit can include an analog/digital converter so as to convert the analog voltage signal into the digital voltage signal; the electronic device can include an analog/digital converter so as to convert the analog voltage signal into the digital voltage signal; and the electronic

Art Unit: 1797

device is used to process the voltage signal is selected from transmission, storage, and analysis or any combination of the three (i.e. [0010]; [0047]-[0069]; p. 4, claim 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. **Claims 2, 10, 12, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber.

With regard to claim 2, while Zilber discloses having specific biomolecules that are detected by his diagnostic device, Zilber does not specifically disclose detecting for a specific compound comprising cholesterol, uric acid, lactate, phospholipids, and triglycerides. It would have been obvious to a person of ordinary skill in the art to modify Zilber's invention by specifically detecting for cholesterol, uric acid, lactate, phospholipids, and triglycerides because Zilber acknowledges the advantage of detecting for various types of biomolecules, which include these recited compounds. Furthermore, it would have been desirable to have a diagnostic device to specifically detect for one of the recited compounds because it would allow the user to quickly identify the analyte of interest in the test sample.

With regard to claims 10, 12, and 14, while Zilber discloses having signal processing components packaged together with the diagnostic device, Zilber does not specifically disclose having a capacitor. It would have been obvious to a person of ordinary skill in the art to modify Zilber by including a capacitor in his device because it would be desirable to have an alternative means of determining the types of signals being received or transmitted by the diagnostic device.

Response to Arguments

15. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1797

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797